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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Mr. Larry Pratt
Regulatory Associate
W.L. Gore and Associates, Inc.
3450 West Kiltie Lane
P.O. Box 500
Flagstaff, Arizona 86002-0500

Re: Reclassification Order
Docket No. 94P-0347
Nonabsorbable Expanded Polytetrafluoroethylene Surgical Suture

Dear Mr. Pratt:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for reclassification of the nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture that is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. FDA concludes that this device and substantially equivalent devices of this generic type, should be reclassified from class III (premarket approval) into class II (special controls). This order, therefore, reclassifies the nonabsorbable ePTFE surgical suture, and substantially equivalent devices of this generic type, into class II under the generic name nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture, effective immediately. This order also identifies the special controls applicable to the device as device-specific labeling and FDA recognized consensus standards.

FDA identifies this generic type of device, the subject of this reclassification, as follows: A nonabsorbable expanded polytetrafluoroethylene (ePTFE) surgical suture is intended for use in soft tissue approximation and ligation, including cardiovascular surgery. It is a monofilament, nonabsorbable, sterile, flexible thread prepared from ePTFE. It may be undyed or dyed with an approved color additive and may be provided with or without an attached needle(s).

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.),* as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 10 l-629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 5 13 of the act (2 1 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

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The 1976 amendments broadened the definition of "device" in 201(h) of the act (21 U.S.C. 32 1 (h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, including the nonabsorbable ePTFE surgical suture, into class III. The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26-27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)). Congress amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). Accordingly, in the Federal Register of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(1)(5)(A) of the act, requiring manufacturers of transitional devices, including the nonabsorbable ePTFE surgical suture, to submit to FDA a summary of, and a citation to, any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information which had not been submitted under section 5 19 of the act (21 U.S.C. 360i). Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply with the reporting requirement by January 13, 1992. Consequently, in the Federal Register of March 10, 1992 (57 FR 8462), FDA extended the reporting period to March 3 1, 1992.

Section 520(1)(5)(B) of the act provides that, after the issuance of an order requiring manufacturers to submit a summary of, and citation to, any information known or otherwise available respecting the devices, but before December' 1, 1992, FDA was to publish regulations either leaving transitional class III devices in class III or reclassifying them into class I or II. Subsequently, as permitted by section 520(1)(5)(C) of the act, in the Federal Register of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993 deadline.

As you know, on September 14, 1994, FDA filed your petition requesting reclassification of the nonabsorbable ePTFE surgical suture from class III into class II. The petition was submitted under section 520(l)(2) of the act (21 U.S.C. 360j(l)(2)), and 21 CFR 860.136 of the agency's regulations. In accordance with section 520(l)(1) of the act, the nonabsorbable ePTFE surgical suture was automatically classified into class III because the nonabsorbable ePTFE surgical suture was a transitional device, i.e., a device previously regulated as a drug. In order to reclassify the nonabsorbable ePTFE surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

Pursuant to 21 CFR 860.125 and 860.136(b)(5), FDA consulted with two members of the General and Plastic Surgery Devices Advisory Committee (the Panel). The Panel members recommended that the nonabsorbable ePTFE surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, be reclassified from class III into class II because the panel members believe that special controls will provide reasonable assurance of the safety and effectiveness of the device. This recommendation was based on the information and data contained in the reclassification petition, on the summary and analysis of the data as set forth in the petition, and on the Panel members' own personal knowledge of, and clinical experience with, the device.

The Panel members identified the following risks to health associated with the use of the device: wound dehiscence, tissue inflammatory response, wound infection, calculogenesis in the urinary and biliary tracts, and suture breakage or knot slippage. They believed these risks to health could be controlled by special controls, specifically FDA recognized consensus standards and device-specific labeling.

FDA identified tissue damage due to suture drag as an additional risk to health associated with the use of the device. FDA has concluded that the nonabsorbable ePTFE surgical suture has the same risks to health as other types of nonabsorbable surgical sutures. These parameters are directly related to the sutures use in soft tissue approximation. They are as follows: suture breakage, wound dehiscence, tissue inflammatory response, suture drag, knot slippage, wound infection, and calculogenesis in the urinary and biliary tracts. FDA also concluded that the ePTFE surgical suture meets all requirements described in the United States Pharmacopeia (USP) Monograph for Nonabsorbable Surgical Sutures, with the possible exception of suture diameter. FDA identified the following FDA-recognized consensus standards and device-specific labeling as special controls for the device:

A. United States Pharmacopoeia (USP) 2 1:

1) Monograph for Nonabsorbable Surgical Sutures;
2) Sutures - Diameter <861>;
3) Sutures – Needle Attachment <871>; and
4) Tensile Strength <881>.

B. Labeling:

1) Contraindication: "This device is contraindicated for use in ophthalmic and neural tissues and for use in microsurgery."
2) "For Single Use Only."
3) If the marketed suture has a different diameter than the diameter specified in USP 21 – Suture Diameter <861>, then a tabular comparison of its diameter and USP suture sizes should be included in the labeling.

After review of the information submitted in the petition and consultation with the Panel members regarding the reclassification petition, FDA has determined that nonabsorbable ePTFE surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, as described and identified herein can be reclassified from class III into class II with the establishment of special controls. FDA believes that class II with special controls will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, FDA is reclassifying the nonabsorbable ePTFE surgical suture intended for use in soft tissue approximation and ligation, including cardiovascular surgery, and substantially equivalent devices of this type into class II. The device is subject to all the general controls of the act and the special controls identified under section 5 13(a)(l)(B) of the act (21 U.S.C. 360c(a)(1)(B)); namely labeling restrictions and FDA recognized consensus standards. Thus, persons who intend to market this device must submit to FDA a premarket notification submission for their nonabsorbable ePTFE surgical suture prior to marketing the device.

A notice announcing this reclassification order will be published in the Federal Register. A copy of this order is on file at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Room l-23, Rockville, MD 20857 and is available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

If you have any questions concerning this reclassification order, please contact Mr. Anthony D. Watson, Plastic and Reconstructive Surgery Devices Branch, at (301) 594-3090. Thank you for your cooperation throughout the reclassification process.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health